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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,563	02/28/2002	Alberto Siccardi	113957-260	5126

7590 12/16/2003

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EXAMINER	
HARMON, CHRISTOPHER R	
ART UNIT	**PAPER NUMBER**
3721	14

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary	Application No.	Applicant(s)	
	10/087,563	SICCARDI, ALBERTO	
	Examiner	Art Unit	
	Christopher R Harmon	3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-50* is/are pending in the application.

4a) Of the above claim(s) *39-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The previous non-final rejection (paper no. 12) is withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 16-17, 24, 27, 30-32, 34, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Kodera (US 4,396,582).

Baldini et al. teach a method for the manufacture and fillings of flexible sterilizable bags comprising printing 2, cleaning 3, and sterilizing of a film 4; aligns the film 4d; welding the film to form a bag 5; welding a valve to the film bag 5b; dosing the bag DOS; filling the bag STO; (figure 2).

In operation, the system forms, sterilizes, fills, and seals printed flexible bags with valves attached. Because the applicant is one of the common inventors of US Patent 4,656,813, the invention and its operation are not discussed here, rather only the improvements upon the invention as understood by the examiner. Baldini et al. do not describe certain limitations claimed by the applicant as improvements upon the commonly owned invention; such as dry cleaning the printed film, humidifying the valve cavity, or using control algorithms for shaping and welding the bags.

Kodera teaches a dry cleaning procedure of a packaging film with purified/filtered air; see figure 5, pump 84. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the dry cleaning procedure as taught by Kodera in the invention of Baldini et al. in order to free the packaging film of foreign substances.

4. Claims 18-20, 28-29, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Kodera as applied to claims 16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Duffey et al. (US 5,129,212).

The modified invention of Baldini et al. does not indicate sterilizing the spouts prior to application to the flexible bag material. Duffey et al. teach a method and apparatus for automatically filling and sterilizing containers in which spouts S are moved along tunnel 122 and sterilized by hydrogen peroxide gaseous medium (column 10, line 7 - column 11, line 33; figures 10-14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to sterilize the spouts prior to applying them to the bag material as taught by Duffey et al. in the modified invention of Baldini et al. in order to maintain a sterile environment throughout the bag manufacturing procedure.

The modified invention of Baldini et al. does not indicate a contribution regulation valve, a constant pressure valve, and a flowmeter. It would have been obvious to one of ordinary skill in the art to include a constant pressure valve for adjusting/regulating the pressure of the system as is well known in the art.

Duffey et al. teach a volume flow meter (not shown) and contribution regulation valve (single head filler valve) 186 operating in a pressurized system (column 13, lines 1-12). A predetermined amount of filling liquid is supplied to the bags accurately.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the flowmeter and valve as taught by Duffey et al. in the modified invention of Baldini et al. to accurately fill the bags.

5. Claims 21-22, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Kodera, and Duffey et al. as applied to claims 18-20, 28-29, and 35 above and further in view of Madsen (US 3,451,403).

The modified invention of Baldini et al., in both instances above, does not disclose detecting electric conductability of the sanitizing solution. Madsen teaches a method and apparatus for determining the purity of a flowing solution or mixture in which "A stream of the solution or mixture is fed into a container after which a diluting or concentrating agent is fed into the container, and measuring means continuously measures the conductivity of the contents of the container." (abstract of the disclosure, lines 3-7). Automatic control means are provided "to switch the feed back to the solution or mixture when the conductivity has declined to a predetermined value..." (abstract of the disclosure, lines 10-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include a system as described by Madsen in either modified invention of

Baldini et al. in order to monitor and control the amount of solution being administered to each bag.

6. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. in view of Kodera, as applied to claims 16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Ogata (GB 2142282 A).

The modified invention of Baldini et al. does not disclose a "heated" printing procedure. Ogata (GB 2142282 A) teaches an automatic packing machine in which " a heated type is pressed against the receiving roll through the packing sheet and printing tape and packing sheet to apply printing to the packing sheet" (claim 1, lines 6-9). It would have been obvious to one of ordinary skill in the art to include the heated printing procedure in the modified invention of Baldini et al. in order to apply printing to the bag material.

7. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. in view of Kodera as applied to claims 16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Brennan et al. (US 4,587,793).

Regarding the limitation of a suspension ring, modified Baldini et al. do not provide for this feature. Brennan et al. (US 4,587,793) teach a bag with a suspension aperture 178 (figure 7) providing for hanging of the bag during the infusion process (column 8, lines 53-54). It would have been obvious to one of ordinary skill in the art, at the time of the invention, to include the suspension aperture as taught by Brennan et al.

in the modified invention of Baldini et al. in order to support the bag during the infusion process.

8. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Kodera as applied to claims 16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Aindow et al. (US 5,934,043).

The modified invention of Baldini et al. provides a ultrasonic welder 21 but does not disclose specifically a piezoelectric transducer, sonotrode, etc. as in claim 45. Aindow et al. teach a web cutting apparatus comprising a ultrasonically vibrated anvil 12 (sonotrode); position transducers 40; and piezoelectric core 142 (figures 5 and 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the various welding elements as taught by Aindow et al. in the modified invention of Baldini et al. in order to seal the web.

Response to Arguments

9. Applicant's arguments with respect to claims 16-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R Harmon whose telephone number is

703-308-8643. The examiner can normally be reached on Monday-Thursday from 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 703-308-2187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

ch

EUGENE KIM
PRIMARY EXAMINER